

Corporate Medical Policy

Sublocade

File Name:	sublocade
Origination:	2/2018
Last CAP Review:	6/2020
Next CAP Review:	6/2021
Last Review:	6/2020

Description of Procedure or Service

Opioid use disorder (OUD) is the diagnostic term used for a chronic neurobiological disease characterized by a problematic pattern of opioid use leading to significant impairment or distress and includes signs and symptoms that reflect compulsive, prolonged self-administration of opioid substances for no legitimate medical purpose or, if another medical condition is present that requires opioid treatment, the opioid is used in doses far greater than the amount needed for treatment of that medical condition.

Sublocade™ is a drug-device combination product that utilizes buprenorphine and the Atrigel Delivery System in a pre-filled syringe. It is injected subcutaneously as a solution by a health care professional and the delivery system forms a solid deposit, or depot, containing buprenorphine. After initial formation of the depot, buprenorphine is released by the biodegradation of the depot. Sublocade provides sustained therapeutic plasma levels of buprenorphine over the one-month dosing interval.

Sublocade should be used as part of a complete treatment program that includes counseling and psychosocial support.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Sublocade when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Sublocade is covered

Sublocade (buprenorphine extended-release) injection, for subcutaneous use may be considered medically necessary when all the following criteria have been met:

- The patient has been diagnosed with moderate to severe opioid use disorder; AND

Sublocade

- The patient is part of a complete treatment program that includes counseling and psychosocial support; AND
- The patient will not be concomitantly receiving opioid medications or Soma (Carisoprodol) while on treatment with Sublocade per the *Sublocade Pharmacy Restriction Policy*; AND
 - To receive therapy with opioid medications or Soma (carisoprodol) will require attestation of sublocade discontinuation and clinical appropriateness per the *Sublocade Pharmacy Restriction Policy*; AND
- The patient has initiated therapy with transmucosal buprenorphine-containing product (delivering the equivalent of 8 to 24mg of buprenorphine daily) over a minimum 7 day period and is stable with clinically controlled cravings and withdrawal symptoms; AND
- The patient will receive monthly treatment with Sublocade with injections no less than 26 days apart.

When Sublocade is not covered

Sublocade is considered not medically necessary and therefore not covered when the criteria listed above are not met.

Policy Guidelines

Sublocade has a boxed warning that provides important safety information, including the risks of intravenous self-administration. If the product were to be administered intravenously rather than subcutaneously, the solid mass could cause occlusion, tissue damage and thrombo-embolic events, including life threatening pulmonary emboli.

Sublocade must be prescribed and dispensed as part of a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the product is not distributed directly to patients. Sublocade will be provided to health care providers through a restricted program, administered only by health care providers in a health care setting, and will require health care settings and pharmacies that dispense Sublocade to complete an enrollment form attesting that they have procedures in place to ensure that Sublocade is dispensed only to health care providers and not directly to patients.

Following transmucosal induction and dose adjustment, the recommended dose of Sublocade is 300 mg monthly for the first two months then a maintenance dose of 100 mg monthly. Maintenance doses may be increased to 300 mg monthly in patients who tolerate the 100 mg dose, but do not demonstrate satisfactory clinical response, as evidenced by positive urine drug screens for illicit opioid use or self-reported illicit opioid use. In the event of a missed dose, the patient should receive the next dose as soon as possible, but no less than 26 days following the previous dose. Occasional delays in dosing up to 2 weeks are not expected to have a clinically significant impact on treatment effect.

In the event the depot must be removed, it can be surgically excised under local anesthesia within 14 days of injection. Only the most recently-injected depot can be removed. Patients who elect to discontinue treatment with Sublocade should be monitored for withdrawal signs and symptoms. Consider transmucosal buprenorphine if needed to treat withdrawal after discontinuing Sublocade.

Billing/Coding/Physician Documentation Information

Sublocade

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J3490, C9399, Q9991, Q9992

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration. Sublocade (buprenorphine extended-release) injection prescribing information. Available at:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209819s0001b1.pdf

Indivior, Sublocade Fact Sheet. Available at: <http://indivior.com/wp-content/uploads/2017/11/SUBLOCADE-Fact-Sheet.pdf>

Indivior Inc. Sublocade (buprenorphine extended-release) injection for subcutaneous use. Prescribing Information. North Chesterfield, VA:Indivior; Revised 3/2018. Available at: <https://www.sublocade.com/Content/pdf/prescribing-information.pdf>. Accessed June 2018.

Specialty Matched Consultant Advisory Panel 6/2018

Specialty Matched Consultant Advisory Panel 6/2019

Specialty Matched Consultant Advisory Panel 6/2020

Policy Implementation/Update Information

- | | |
|---------|--|
| 3/9/18 | New policy developed. Sublocade (buprenorphine extended-release) injection, for subcutaneous use may be considered medically necessary when: the patient has been diagnosed with moderate to severe opioid use disorder; AND the patient is part of a complete treatment program that includes counseling and psychosocial support; AND the patient will not be concomitantly receiving opioid medications or Soma (Carisoprodol) while on treatment with Sublocade per the <i>Sublocade Pharmacy Restriction Policy</i> ; AND the patient has initiated therapy with transmucosal buprenorphine containing product (delivering the equivalent of 8-24mg of buprenorphine daily) over a minimum 7 day period and is stable with clinically controlled cravings and withdrawal symptoms; AND the patient will receive monthly treatment with Sublocade with injections no less than 26 days apart. (an) |
| 7/13/18 | Codes Q9991, Q9992 added to Billing/Coding section effective 7/1/2018. Updated Policy Guidelines section to reflect recommended dosing. Reference added. Specialty Matched Consultant Advisory Panel review 6/27/2018. No change to policy statement. (krc) |
| 7/30/19 | Specialty Matched Consultant Advisory Panel review 6/19/2019. No change to policy statement. (krc) |
| 8/11/20 | Specialty Matched Consultant Advisory Panel review 6/17/2020. (krc) |

Sublocade

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.